Section 3. Documentation Requirements

Study staff are responsible for proper collection, management, storage, quality control, and quality assurance of all study-related documentation. This section contains information on the Essential Documents that the study site must maintain throughout the study. It also contains information related to establishing adequate and accurate participant research records for MTN-016.

3.1 Essential Documents

The Division of AIDS (DAIDS) Standard Operating Procedure (SOP) for Essential Documents specifies the essential documents that study site must maintain for DAIDS-sponsored studies, including MTN-016. When required documents are modified or updated, the original and all modified or updated versions must be maintained. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location.

Section Appendix 3-1 presents a suggested essential documents filing structure for MTN-016. The study site is not required to adopt the suggested structure, but is encouraged to consider it when developing their filing approach for MTN-016. The study site also is encouraged to establish an SOP to document their filing approach. Further clarifications of the suggested filing structure are as follows:

- Essential documents may be stored in files and/or in binders. The files/binders listed in Section Appendix 3-1 may be further subdivided, consolidated, and/or re-organized if desired.

- It is recommended that a table of contents be developed and maintained in the front page(s) of each file/binder. Within each section of the file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).

- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders (see items 23-25 in Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories. The list of documents to be kept in the lab should be included in the master table of contents and incorporated into the master file at the close of the study.

- The suggested filing structure assumes that MTN-016 participant case history records will be stored separately from the other essential documents listed in Section Appendix 3-1. Section 3.2 below provides information on the required contents of these records. The suggested filing structure also assumes that the MTN-016 Screening and Enrollment Log and Participant Name-ID Number Link Log (which are described in Section 4 of this manual) will be stored in the study clinic or data management area and not necessarily with the other essential documents listed in Section Appendix 3-1.

3.2 Participant Case History Documentation

The study site must maintain adequate and accurate case history records for each study participant.

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

- Basic participant identifiers.
- Documentation of appropriate written informed consent for the participation of each woman and infant in the study prior to the conduct of any study procedures per site SOP.
- Documentation that the woman and infant study participants met the study's eligibilityrequirements by confirming each inclusion and exclusion criterion individually, either through chart note or use of the eligibility checklist.
- A record of all contacts, and attempted contacts, with the participant/infant.
- A record of all procedures performed by study staff during the study.
- Study-related information on the participant's condition before, during, and after the study, including:
  - Data obtained directly from the participant (e.g., interview responses and other self-reported information)
  - Data obtained by study staff (e.g., exam and lab findings)
  - Data obtained from non-study sources (e.g., non-study medical records)

In addition to the above, DAIDS requires that all protocol departures/deviations/violations be documented in participant records, along with reasons for the departures/deviations/violations and/or attempts to prevent or correct the departures/deviations/violations, if applicable The MTN policy on protocol deviations and the MTN Manual of Operational Procedures should be referenced for complete guidance on protocol deviations.

Once sites are operating under v2.0 of the MTN-016 protocol, the Protocol Deviation Log CRF will be used to document each protocol deviation. The Protocol Deviation Log CRF is completed and faxed to the SDMC for each reportable deviation identified. Like all CRFs, completed Protocol Deviation Log CRFs will be filed in the participant's study binder. Missed visits are considered protocol deviations per the MTN policy, however these will *not* be captured on the Protocol Deviation Log CRF for MTN-016 (the Woman/Infant Missed Visit CRFs will capture this information instead). As corrective and preventive action plans are required components of protocol deviation documentation, it is important to ensure that chart notes or other source documentation documents the associated counseling that accompanies missed visits.

If there is any question as to whether a deviation has occurred, or how it should be documented, MTN Regulatory (mtnregulatory@mtnstopshiv.org) should be consulted. Once the potential protocol deviation has been confirmed by the MTN Regulatory Department, the site will be contacted with this confirmation and ideally fax the completed CRF within 7 days. Once the CRF is faxed, the MTN Regulatory department or the study management team will follow up with the site regarding any next steps as needed.

It is recommended that sites report in an expedited manner to IRBs/ECs PDs that pose a potential safety risk to a participant(s) and those that could affect the integrity of the study according to the local IRBs/ECs' standard operating procedures and guidelines.

It is also recommended that a complete list of all PDs occurring at the site, including PDs not meeting immediate reporting standards noted above, be submitted to the local IRBs/ECs in accordance with their reporting policies. If a local IRB/EC does not have a specific reporting policy, MTN recommends that this be done at the time of IRB renewal submission, annually or semi-annually per local requirements. These listings will be provided by MTN to the sites on request. Sites should request these PD listings from SCHARP at least two weeks prior to the planned date of submission to their local IRBs/ECs.

3.2.2 Source Data and Source Documentation

The International Conference on Harmonization Consolidated Guidance for Good Clinical Practice (ICH-E6) defines the terms source data and source documentation as follows:

Source data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source documents: Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies of transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the trial).

Certified Copies: Copies of documents, with manual documentation that all material included on the copy is accurate and complete based on the source document. The note is then dated and signed by the copier. This is not ideal given that corrections, clarifications, or additional material may later be added to a source document, rendering the certified copy accurate and complete only as of the date it was copied. Note that for a copy to be certified, the entire document must be visible, i.e. use of the reduce feature on the copier may be required, while ensuring that full legibility is maintained.

Source documents are commonly referred to as the documents —paper-based or electronic — upon which source data are first recorded. The study site must adhere to the standards of source documentation specified in the DAIDS SOP for Source Documentation. The DAIDS SOP specifies both requirements and recommendations. The study site must comply with all requirements and is encouraged, but not required, to comply with all recommendations.

It is expected that participant case history records will consist of the following source documents:

- Narrative chart notes
- Visit checklists and/or other site-specific flowsheets
- Local laboratory testing logs and result reports
- DataFax and Non-DataFax forms provided by the MTN Statistical and Data Management Center (SDMC)
- Other source documents (e.g., site-specific worksheets, non-study medical records)

As a condition for study activation, the study site must establish a site SOP for source documentation, approved by FHI 360 360 and SCHARP, that specifies the use of the above-listed documents as source documents. Although it is the responsibility of the site to determine the most appropriate source document for each required case history element, Appendix 3-2 provides a guide that the site may follow for this study. Supplemental information on the use of chart notes, visit checklists, and forms provided by the MTN SDMC is provided below. Detailed information on proper completion of DataFax and Non-DataFax forms provided by the MTN SDMC is provided in Section 13 of this manual.

Chart Notes: Study staff must document every contact with a study participant in a signed and dated chart note specifying the date, type, purpose, and location of the contact, and the general status of the participant. Any specific procedures conducted and, when necessary, adherence to protocol requirements should also be documented. Chart notes also must be used to document the following:

- The study informed consent process (if an Informed Consent Coversheet is not used) and that informed consent was completed prior to initiation of any study procedures (see also Section 5),
- Procedures performed that are not recorded on other source documents or procedures required per protocol which were not performed, and the reason why,
- Pertinent data about the participant that are not recorded on other source documents,
- Protocol departures/deviations/violations that are not otherwise captured on other source documents

The study site is strongly encouraged to adopt a common format for all chart notes, to help ensure adequacy and consistency of note content and maximize adherence to GCP standards.

Laboratory: Each lab test must have a defined source document which is the first place the result is recorded or generated. For assessment of eligibility and HIV status data for MTN-016, certified copies of parent protocol lab results may be used. The certified copy must be of the form identified as source for the parent protocol, i.e., if specific test results will be logged directly onto a CRF form, that CRF will be source. Site Source Documentation SOPs for MTN-016 must list which sources will be used and should reflect source documentation processes consistently with parent protocol documentation processes outlined in the site SOP. Certified copies must be fully legible and contain the full document serving as source, i.e., no run-offs or cut off sections of the original.

Visit Checklists: The checklists in Section 7 of this manual represent convenient tools to fulfill the requirement of documenting all study procedures performed with each study participant. Note, however, that checklists alone are not sufficient for documenting all procedures. For example, chart notes are required to document procedures performed at unscheduled study visits, and/or to explain why procedures in addition to those listed on a checklist may have been performed or why procedures listed on a checklist were not performed. Chart notes also may be required to document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements). The site may elect to create source worksheets to ensure full documentation for all data points is collected for study visits and for study visits involving data collection for multiple protocols. FHI 360 should approve these alternate source worksheets prior to implementation. Use of source worksheets should be referenced in the site-specific Source Documentation SOP.

DataFax and Non-DataFax Forms Provided by the MTN SDMC: The case report forms for this study are designed for use with the DataFax data management system described in Section 13 of this manual. See Section Appendix 3-4 for a listing of all DataFax and non-DataFax forms to be provided for this study.

The SDMC will provide an initial supply of all CRFs to each site. Additional supplies will be printed at each site, and the CRFs will be available via the ATLAS web portal.

As shown in Appendices 3-4 and 3-5, many of the DataFax and non-DataFax forms provided by the SDMC have been designed to serve as source documents. The study site must document the forms that it will routinely use as source documents for this study in its Source Documentation SOP, and they must follow the specifications of this SOP consistently for all study participants. In the event that study staff is not able to record data directly onto forms designated as source documents, the following procedures should be undertaken:

- Record the data onto an alternative source document
- Enter the alternative source document into the participant’s study chart, if site policy permits. If site policy does not permit, either a note to file documenting location of source or a certified copy of the source document should be made and filed with the study chart.
- Transcribe the data from the alternative source document onto the appropriate form
- Enter a chart note stating the relevant study visit date and the reason why an alternative source document was used

3.2.3 Document Organization

Study staff must make every effort to store all study records securely and confidentially. Case history records must be stored in the same manner for all participants, in areas with access limited to authorized study staff only. Study staff are responsible for purchasing file folders, binders, storage cabinets, and any other equipment or supplies needed to properly store all records.

Study-related documentation collected during the screening process should be stored in file folders or thin notebooks for each potential participant. All screening documentation — for potential participants who eventually enroll in the study as well as for those who do not enroll — must be maintained and available for monitoring throughout the study. For participants who enroll in the study, their screening documentation should be transferred into large ring binders that will serve as participants' study notebooks for the duration of their participation in the study.

All documents contained in participant case history records must bear a participant identifier, which generally will consist of either the participant identification number (PTID) or the participant name. . As a best practice, it is recommended that records bearing names or other personal identifiers, such as locator forms and informed consent forms, are stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location must be identified by PTID only, with the exception of medical information being forwarded to a participant's outside-study physician for the purpose of medical history or for referral for follow-up care.

Regardless of whether the identifier on a particular document consists of the participant name or PTID, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated on copies of original source documents. For example, if medical records obtained from a non-study health care provider bear the participant's name, the original documents bearing the name must be stored unaltered with other study documents bearing the name. However, a copy of the original documents could be made, the PTID could be entered onto the copies, and then the participant name could be obliterated from the copies. Copies handled in this way could then be stored in participants' study notebooks and/or transferred or transmitted to non-study site locations.

All on-site databases must be secured with password-protected access systems. Any lists, logbooks, appointment books, or other documents that link PTIDs to other participant identifiers should be stored securely in a location separate from records identified by either participant name or PITD. When in use, these documents should not be left unattended or otherwise accessible to study participants, other study clinic patients, or any other unauthorized persons.

As a condition for study activation, the study site must establish an SOP for data management. This SOP minimally should contain the following elements:

- Procedures for assigning PTIDs, linking PTIDs to participant names, and storing the name-PTID link log.
- Procedures for establishing participant files/charts/notebooks.
- During-visit participant chart and case report form review procedures.
- Post-visit participant chart and case report form review procedures and timeframes.
- Data transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted.
- Procedures for resolving data quality control notes from the SDMC.
- Procedures for handling and filing field workers' logs, worksheets, etc. (if applicable).
- Storage locations for blank case report forms.

- Storage locations for documents identified by participant names or other personal identifiers.
- Storage locations for documents identified by PTID.
- Procedures for back up of electronic study data (if applicable).
- Handling of participant study records for off-site contacts and visits (if applicable).
- Confidentiality protections.
- Other ethical and human subjects considerations.
- Staff responsibilities for all of the above (direct and supervisory).
- Staff training requirements (if not specified elsewhere).
- QC/QA procedures related to the above (if not specified elsewhere).

3.3 Record Retention Requirements

All records must be retained on-site throughout the study's period of performance, and for at least three years after completion or termination of the study. DAIDS will provide further instructions for long-term storage of study records after the study is completed.

Section Appendix 3-1
Suggested Filing Structure for MTN-016 Essential Documents

File/Binder #1: MTN-016 Protocol and Current Informed Consent Form

1. MTN-016 Protocol (including copy of signed and dated protocol signature page): Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments issued after Version 1.0
2. Currently-approved MTN-016 informed consent form(s), plus all previously IRB-approved forms (e.g., Comprehension Surveys), with a version control log listing dates of all approved ICFs and associated Comprehension Surveys, with a summary of updates

File/Binder #2: Regulatory Authority Documentation (if applicable)

3. Regulatory Authority Correspondence/Authorization/Approval/Notification of Protocol (if applicable; if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)

File/Binder #3A: IRB/EC Documentation for [IRB/EC A]

4. FWA documentation for IRB/EC A
5. Roster of IRB/EC A, including updates throughout course of site participation in study (if available)
6. Relevant IRB/EC A Submission Requirements/Guidelines/SOPs, including updates throughout course of site participation in study
7. IRB Correspondence for IRB/EC A: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.

File/Binder #3B: IRB/EC Documentation for [IRB/EC B]

8. FWA documentation for IRB/EC B
9. Roster of IRB/EC B, including updates throughout course of site participation in study (if available)
10. Relevant IRB/EC B Submission Requirements/Guidelines/SOPs, including updates throughout course of site participation in study
11. IRB Correspondence for IRB/EC B: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.

File/Binder #4: MTN-016 Study-Specific Procedures (SSP) Manual

12. Final version 1.0 (when available) and any subsequent updates
    Notes:
    - For this reference copy of the SSP Manual, do not discard out-dated pages or sections when updates are issued; retain all versions of all pages as a complete historical record.
    - The SSP Manual contains reference versions of all study case report forms, therefore additional (blank) copies of the case report forms need not be stored elsewhere in the essential document files.

File/Binder #5: MTN-016 Study-Specific Standard Operating Procedures

13. Final approved version of each SOP, and any subsequent updates to each

File/Binder #6: MTN-016 Staffing Documentation

14. DAIDS Investigator of Record Form (copy of original and dated form submitted to the RCC for Protocol Registration, and any subsequent updates)
15. MTN-016 Investigator of Record CV (copy of CV submitted to the RCC for Protocol Registration; ensure that the CV is current prior to initiating MTN-016; it is recommended that CVs be signed and dated to document at least annual updating)
16. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
17. Study Staff Roster (original submitted to MTN CORE for study activation, and any subsequent updates)
18. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
19. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
20. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-016; it is recommended that CVs be signed and dated to document at least annual updating)
21. Study Staff Job Descriptions
22. Documentation of Study Staff Training and refresher training, including the date, details of material covered, who provided the training, and which staff were in attendance

Section Appendix 3-1
Suggested Filing Structure for MTN-016 Essential Documents

File/Binder #7: Local Laboratory Documentation

23. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
24. Copy of local laboratory normal sheets, dated, and updated as required through dates of site study activity.
25. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7)

    Note:
    - It is recommended that a cross-reference be included in this file/binder specifying the storage location(s) of other lab-related essential documents filed in the local lab(s).

File/Binder #8: Monitoring Visit Documentation

26. Monitoring Visit Log, if applicable.
27. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings, if applicable.

File/Binder #9: Documentation of Other MTN Site Visits

28. (Non-Monitoring) Site Visit Log
29. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings
30. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
31. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
32. Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #10: Study-Related Sponsor Communications

33. Study-Related Communications to and from DAIDS
34. Communications to and from DAIDS RCC (includes copies of all submissions to the DAIDS Protocol Registration Office, which will be prepared by the site with copies provided to the MTN CORE, as well as the current monthly DAIDS IB/PI listing and year-end and current monthly DAIDS Comprehensive Safety Distribution Report)

    Notes:
    - Communications related to individual MTN-016 study participants will be filed in individual participant study records.

File/Binder #11: Other Study-Related Communications

35. Study-Related Communications to and from MTN CORE
36. Study-Related Communications to and from MTN SDMC
37. Study-Related Communications to and from MTN Network Lab
38. Other Study-Related Communications

    Notes:
    - Communications related to individual MTN-016 study participants will be filed in individual participant study records.
    - Product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy, and may be incorporated into Master Regulatory Files for archival at completion of study.

File/Binder #12: Study Site Staff Meeting Documentation

39. MTN-016 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

File/Binder #13: Conference Call Documentation

40. MTN-016 Protocol Team and Protocol Co-Chairs Conference Call Summaries if applicable
41. MTN-016 Study Coordinators Group Conference Call Summaries if applicable
42. MTN-016 Laboratory Group Conference Call Summaries if applicable
43. MTN-016 Community Educators Group Conference Call Summaries if applicable
44. Summaries of Other MTN-016 Conference Calls

File/Binder #14: DAIDS and Other Reference Documentation

45. DAIDS SOP for Source Documentation (Version 2.0 and any subsequent updates)
46. DAIDS SOP for Essential Documents (Version 2.0 and any subsequent updates)
47. DAIDS Protocol Registration Policy and Procedures Manual (August 2004 and any subsequent updates)
48. US Regulations Applicable to Conduct of MTN-016 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
49. Any other relevant manuals or reference documents

File/Binder #15: Site-Specific Study Activation Documentation

50. Site-Specific Study Activation Documents

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN-016

Required Case History Element	Source Documents*
Basic participant identifiers.	Locator form; Demographics forms.
Documentation that the participant provided written informed consent to screen for and participate in the study.	Signed and dated informed consent forms Comprehension Surveys, and Cover Sheets; signed and dated chart notes stating that informed consent was obtained prior to initiating study procedures.
Documentation that the participant met the study selection (eligibility) criteria.	Woman and Infant Eligiblity Checklists, Exclusion Criteria Item #1 only; parent protocol source for pregnancy test lab results, Woman Enrollment Form, Woman Demographics form, Parent Protocol Participation, Woman Medical History Log, Infant Medical History Log, signed and dated chart notes.
A record of all contacts, and all attempted contacts, with the participant.	Signed and dated chart notes, and/or other worksheets or site-specific documents if designated in site SOPs.
A record of all procedures performed by study staff.	Completed visit checklists; signed and dated chart notes detailing (i) procedures performed in addition to those contained on the checklist and/or (ii) the reason why procedures contained on the checklist were not performed.
Information on the participant's condition before, during, and after the study.	All documents listed above; Woman Concomitant Medications Log form, Woman Demographics, Genetic Screening History form (women), Pregnancy Report and History form, Pregnancy Outcome, Woman Missed Visit form, Woman Medical History form, Infant Concomitant Medications Log form, Infant Visit form, Infant Physical Exam form, , Infant Missed Visit form; local lab logs and result reports from the local lab (infants); results of information pertinent to the study obtained from non-study sources; signed and dated chart notes.

*Other site-specific source documents also may be used. Note: CRFs listed may not be used as source if information is first reported elsewhere and then transcribed to the form. Site-specific source documentation will be described in detail in each site's Source Documentation SOP.

Section Appendix 3-3
MTN-016 DataFax and Non-DataFax Forms

MTN-016 DataFax Forms	
Woman Demographics	Woman End of Study Inventory
Woman Enrollment	Woman Termination
Woman Subsequent Consent	Infant Enrollment
Parent Protocol Participation	Infant Visit
Genetic Screening History	Infant Physical Exam
Ultrasound Results	
Woman Follow-up Visit	Infant HIV Test Results
Woman Interim Visit	Infant Interim Visit
Woman Concomitant Medications Log	Infant Concomitant Medications Log
Pregnancy Report and History	Infant Missed Visit
Pregnancy Outcome	Infant Participant Transfer
Woman Missed Visit	Infant Participant Receipt
Woman Participant Transfer	Infant End of Study Inventory
Woman Participant Receipt	Infant Termination
Woman End of Study Inventory	Social Harms Assessment Log
MTN-016 Non-DataFax Forms	
Woman Medical History Log	Infant Medical History Log

Section Appendix 3-4
Use of MTN-016 DataFax Forms as Source Documents

In some cases the parent protocol CRF may serve as source via certified copy, however note that some MTN-016 CRFs require more detail than the parent protocol forms provide.		
MTN-016 DataFax Forms	**Source?**	**Comments**
Woman Demographics	Yes	Form is interviewer-administered; participant's responses are recorded directly onto the form.. Questions should NOT be certified copied from MTN-003, but updated by verbal participant report.
Woman Enrollment	No	All items are based on parent protocol or participant informed consent form.
Woman Subsequent Consent	No	All items are based on parent protocol or participant informed consent form.
Parent Protocol Participation	No	All items are based on parent protocol or other study documents.
Genetic Screening History	Yes	Form may be source for all items.
Ultrasound Results	No	All items are based on ultrasound report
Woman Follow-up Visit	No	All items are based on data recorded on other source documents.
Women Interim Visit	No	All items are based on data recorded on other source documents.

Section Appendix 3-4
Use of MTN-016 DataFax Forms as Source Documents

In some cases the parent protocol CRF may serve as source via certified copy, however note that some MTN-016 CRFs require more detail than the parent protocol forms provide.		
MTN-016 DataFax Forms	**Source?**	**Comments**
Woman Concomitant Medications Log	Yes	Form is completed primarily based on participant self-report; participant responses are recorded directly onto the form. If medical records are available to document participants' use of medications, these records also will be used as source. If available medical records do not agree with participant reports of use of medications, the medical records will be used as source and any discrepancies with participant report will be documented in chart notes.
Pregnancy Report and History	Mixed	Items 1, 2 and 3 may be based on source data from parent protocol, May be source for items 4 and 5.
Pregnancy Outcome	Mixed	Medical records ideally will be obtained to document pregnancy outcomes. When such records are obtained, they will serve as source for data recorded on this form. Otherwise, the form will serve as source for recording participant-reported pregnancy outcome data.
Social Harms Assessment Log	Yes	Form is interviewer-administered; participant responses may be recorded directly onto the form.
Woman Missed Visit	Yes	Form may be source for the fact that the visit was missed; source data on the reason why the visit was missed also may be recorded on this form.
Woman Participant Transfer	No	All items are based on data recorded on other source documents.
Woman Participant Receipt	No	All items are based on data recorded on other source documents.
Woman End of Study Inventory	No	All items are based on data recorded on other source documents.
Woman Termination	No	All items are based on data recorded on other source documents.
Infant Enrollment	Mixed	Item 4 may be source. All other items are based on source data recorded on participant informed consent form or Pregnancy Outcome Form.
Infant Visit	Mixed	May be source for items 1-4. Items 5-8 are based on data recorded on other source documents.
Infant Physical Exam	Yes	May be source for all items.
Infant HIV Test	No	All items are based on data recorded on other source documents.
Infant Interim Visit	No	All items are based on data recorded on other source documents.
Infant Concomitant Medications Log	Yes	May be source for all items.

Section Appendix 3-4
Use of MTN-016 DataFax Forms as Source Documents

In some cases the parent protocol CRF may serve as source via certified copy, however note that some MTN-016 CRFs require more detail than the parent protocol forms provide.		
MTN-016 DataFax Forms	**Source?**	**Comments**
Infant Missed Visit	Yes	Form may be source for the fact that the visit was missed; source data on the reason why the visit was missed also may be recorded on this form.
Infant Participant Transfer	No	All items are based on data recorded on other source documents.
Infant Participant Receipt	No	All items are based on data recorded on other source documents.
Infant End of Study Inventory	No	All items are based on data recorded on other source documents.
Infant Termination	No	All items are based on data recorded on other source documents.

Section Appendix 3-5
Use of MTN-016 Non-DataFax Forms as Source Documents

MTN-016 DataFax Forms	**Source?**	**Comments**
Woman Medical History	Yes	Form is source for all items; chart notes also will be used as needed to further document the details of condition recorded on this form. For co-enrolled participants, certified copies of parent study medical history source documents may be used as source.
Infant Medical History	Yes	All items based on verbal report from mother/guardian.